

Attorney Docket No.: DC-0190
Inventors: Hamilton and Stanton
Serial No.: 10/089,475
Filing Date: August 12, 2002
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REMARKS

Claim 9 is pending in the instant application. Claim 9 has been rejected. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Rejection of Claims Under 35 U.S.C. §103

Claim 9 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Moyer et al. (1999), in view of Riordan et al. (WO 01/03722), Cormack et al. (1996), McCray et al. (U.S. Patent No. 6,855,549; hereafter referred to as the '549 patent), Chou et al. (1991), Dalemans et al. (U.S. Patent No. 6,136,594; hereafter referred to as the '594 patent), and Caplan et al. (U.S. Patent Application No. 2004/0266883). The Examiner suggests that Moyer et al. (1999) teach a method of measuring the effect of butyrate on the expression of a CFTR-GFP. It is suggested that because the specification does not define EGFP, this claim limitation is met by Moyer et al. The Examiner acknowledges that Moyer et al. do not teach the mutant human $\Delta F508$ CFTR protein, the method of using proximal human CFTR promoter region or the specific species of EGFP reporter gene, as well as failing to teach the use of an anthracycline agent in the method. It is suggested, however, that Riordan et al. teach a method for increasing the amount of CFTR on cell surface of a cell by contacting with an agent, wherein the cells express $\Delta F508$ CFTR protein. It is further suggested that Cormack et al. teach the cloning of GFP mutants, which fluoresce more intensely

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than wild-type GFP, wherein McCray et al. teach the cumulative of Cormack et al. of an EGFP reporter construct with the CFTR. In addition, it is suggested that Chou et al. teach the transcription regulatory elements of the CFTR gene and that one was a proximal positive element delimited by the 5' deletion constructs -226 base pairs upstream of the transcription start site. Furthermore, Dalemans et al. are suggested to teach a vector for expression in a cell comprising the human CFTR gene which is under control of the endogenous human CFTR promoter, wherein it is suggested that Dalemans et al. teach that $\Delta F508$ is a mutant allele which is expressed at low levels and associated with disease of CF. The Examiner has then suggested at page 3 of the Office Action dated September 9, 2008 that "Moyer et al." teach a method of using anthracycline to induce $\Delta F508$ CFTR, however, Applicants believe the Examiner has meant to cite Caplan et al. Applicants respectfully traverse this rejection.

Under 35 U.S.C. §103, the factual inquiry into obviousness requires a determination of: (1) the scope and content of the prior art; (2) the differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) secondary considerations. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966). Additionally, under 35 U.S.C. 103, the references combined to establish a case of obviousness must have been published or made public before the priority date of the instant application. In the case of the instant application, the priority date is

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October 6, 1999. However, the reference of Caplan et al. (U.S. Patent Application No. 2004/0266883) has a filing date of March 11, 2004 and a priority date of October 27, 1999. Therefore, the reference of Caplan et al. is not a valid prior art reference because it antedates the priority date of the instant application. Therefore, the rejection under 35 U.S.C. 103(a) must rely only on the references of Moyer et al. (1999), Riordan et al. (WO 01/03722), Cormack et al. (1996), McCray et al. (U.S. Patent No. 6,855,549), Chou et al. (1991), and Dalemans et al. (U.S. Patent No. 6,136,594).

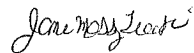
In the response dated June 9, 2008, Applicants responded to a rejection of claim 9 under 35 U.S.C. 103(a) over this same combination of prior art (Moyer et al., Riordan et al., Cormack et al., McCray et al., Chou et al., and Dalemans et al.). In response to that rejection, Applicants amended claim 9 to refer to use of an anthracycline agent in the method of the present invention. As discussed in that June 9, 2008 reply, and as acknowledged by the Examiner in the present Final Rejection, nowhere does the combination of Moyer et al., Riordan et al., Cormack et al., McCray et al., Chou et al., and Dalemans et al. teach or suggest use of an anthracycline agent as claimed. Therefore, the combined teachings of the cited documents, without Caplan et al., cannot be held to make the present invention obvious. Reconsideration and withdrawal of this rejection is therefore respectfully requested.

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II. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,



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